JUN - 1 2001

K011366

# 510(K) Summary for the Siemens Custom TCI-Combi

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|---|---|---|
| 1. | **Applicant's Name & Address:** | Siemens Hearing Instruments<br>10 Constitution Ave.<br>PO Box 1397<br>Piscataway, NJ 08855 |
| 2. | **Contact Person, Telephone and e-mail Address:** | Dave Slavin<br>732-562-6658<br>dslavin@siemens-hearing.com |
| 3. | **Device Trade of Proprietary Name:** | Custom TCI-Combi<br>(Tinnitus Control<br>Instrument Combination) |
| 4. | **Device Common Name / Classification Name:** | **Hearing Aid, Air Conduction and Tinnitus Masker** |
| | **Product Code:** | **ESD and KLW** |
| 5. | **Establishment Registration Number:** | 2217809 |
| 6. | **Address of Manufacturing Site:** | Siemens Hearing Instruments<br>10 Constitution Ave.<br>PO Box 1397<br>Piscataway, NJ 08855 |
| 7. | **Classification of Device:** | Class II |
| 8. | **Marketed Devices to which the claim of substantial equivalence is made:** | K 97229<br>Siemens Hearing Instruments<br>Prisma Hearing Instrument<br>& K974751<br>General Hearing Instruments<br>Tranquil Tri-OE |

**9. Compliance with Section 514, Performance Standards:** Not Applicable

**10. Indications for Use:**

The Custom TCI-Combi is an in-the-ear style electronic, air conduction broad-band noise generator and hearing aid intended to output noise of sufficient intensity and bandwidth to be used for tinnitus habituation therapy and is also suitable for tinnitus masking therapy. Custom TCI-Combi is intended to be used by those individuals who experience tinnitus and desire amplification. This device is fit by a qualified audiologist or other hearing healthcare professional familiar with the diagnosis of tinnitus and subsequent rehabilitation therapy.

The target population is primarily the adult population over 18 years of age. The target group for this product includes individuals reporting tinnitus who do need amplification. This product may also be used with children 5 years of age or older.

**11. Description of Device:**

Custom TCI-Combi is a fully digital, low-level noise generator that was developed to be used along with appropriate counseling and/or tinnitus therapy. This product is available in a full in-the-ear shell, half shell, or in-the-canal shell style. It is programmable, with selectable noise and output levels. The output noise can be custom-tailored to the user's individual requirements. The Custom TCI-Combi is also a digital programmable hearing aid which provides sound amplification. This hearing aid is a four-channel instrument with wide dynamic range compression. The product has two programs that can be programmed independently to noise masker only, amplification only or both noise masker and sound amplification.

**12. Comparison Information to Predicate Device:**

Custom TCI-Combi is the combination of a tinnitus masker and a conventional hearing instrument. Thus, two devices are specified here as predicate devices. The tinnitus masker portion of the Custom TCI-Combi is predicated by General Hearing Instruments Tranquil Tri-OE. The hearing instrument portion of the Custom TCI-Combi is predicated by Siemens Hearing Instruments Prisma hearing aid.

The Custom TCI-Combi is substantially equivalent to the General Hearing Instruments Tranquil TRI-OE (K974751). The Tranquil is also a noiser for tinnitus, with no amplification characteristics. The primary difference between the Siemens Custom TCI-Combi and the Tranquil is that the Custom TCI-Combi is digital with programmable noise characteristics which increases the flexibility of the device.

The Custom TCI-Combi is equivalent to the Siemens Hearing Instruments Prisma hearing instrument. The programmable hearing instrument parameters of the Custom TCI-Combi are the same as the programmable parameters of the Prisma.

The following table compares the Siemens Hearing Instruments Custom TCI-Combi device to the predicate devices – General Hearing Instruments Tranquil Tri-OE and Siemens Hearing Instruments Prisma.

| | Siemens Hearing Instrument Custom TCI-Combi Device | Predicate Device:<br><br>General Hearing Instruments Tranquil Tri-OE (GHI)<br><br>and<br><br>Siemens Hearing Instruments (SHI) Prisma |
|---|---|---|
| Intended Use | Mask tinnitus as part of tinnitus management program<br><br>Provide amplification for compensation of hearing loss | Mask tinnitus as part of tinnitus management program (GHI)<br><br>Provide amplification for compensation of hearing loss (SHI) |
| Target Population | Adults and children (≥5 years) with tinnitus and hearing loss that are participating in a tinnitus management program | **GHI** Adults with tinnitus and hearing loss that are participating in a tinnitus management program<br>**SHI** Adults and children with hearing loss |
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|---|---|---|---|
| Operation | | **GHI** | **SHI** |
| Circuit type | Digital | Analog | Digital |
| Programmable | Yes | No | Yes |
| Available noises | One | One | |
| Volume control | Yes | Yes | Yes |
| Number of channels | Four | | Four |
| Variable compression kneepoint | Yes | | Yes |
| Variable compression ratio | Yes | | Yes |
| Multiple programs/memories | Yes | | Yes |
| Physical Description | Custom product, available as in-the-ear, half shell, and in-the-canal shell styles | Custom product, available as in-the-ear and mini-canal shell styles (GHI)<br><br>Custom product, available as in-the-ear, half shell, in-the-canal, mini-canal, and completely-in-the-canal shell styles (SHI) | |
| Output Characteristics | | | |
| Noiser | In-the-ear: 89 dB Broadband noise<br><br>In-the-canal and half shell: 84 dB Broadband noise | 75 dB SPL High-tone noise (GHI) | |
| Hearing aid amplifier | In-the-ear: 105 dB HF-Average OSPL 90 (ANSI S3.22-1996) (110/40/03 matrix)<br><br>In-the-canal and half shell: 107 dB HF-Average OSPL 90 (ANSI S3.22-1996) (110/35/03 matrix) | In-the-ear, half shell, in-the-canal:<br>107 dB HF-Average OSPL 90 (ANSI-S3.22-1996) (113/40/03 matrix) | |
| Volume control range | Programmable: OFF, 8 dB, 16 dB, 32 dB | 40 dB | |

**Custom TCI-Combi Comparison with Predicate Devices**

**13. Information required under Title 21, Section 874.3400, and not already provided above.**

Risks

In-the-ear : The maximum output for the in-the-ear model of the noise masker is 88 dB measured with an A-weighted filter. As the noise may be on continuously and as the noise level does fall into the range which can cause hearing loss (OSHA Regulations (Standard – 29 CFR 1910.95 Occupational Noise Exposure)), warnings are included in the Technical Information for the Hearing Health Professional and in the User's Manual for the consumer.

Half shell and In-the-canal: There are no risks associated with this device because the output of the noiser does not exceed OSHA exposure limits (OSHA Regulations, Standard – 29 CFR 1910.95 Occupational Noise Exposure).

Hearing Healthcare Professional Diagnosis:
The sale and fitting of the Siemens Custom TCI-Combi will only be conducted through a Hearing Healthcare Professional, such as an audiologist or otolaryngologist.

Benefits:
Relief of tinnitus symptoms may be provided by this device when utilized with appropriate counseling and/or tinnitus therapy. Sound amplification may be of benefit to the individual with hearing loss when programmed for the user's hearing loss.

Warnings for Safe Use

In-the-ear: As the noise may be on continuously and as the noise level does fall into the range which can cause hearing loss (OSHA Regulations (Standard – 29 CFR 1910.95 Occupational Noise Exposure)), warnings are included in the Technical Information for the Hearing Health Professional and in the User's Manual for the consumer. General use precautions are in the User's Manual.

Half shell and In-the-canal: As this device cannot deliver damaging sound intensity, no warning is required about sound output level. General use precautions are in the User's Manual.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 1 2001

Siemens Hearing Instruments
c/o Dave Slavin
10 Constitution Avenue
P.O. Box 1397
Piscataway, NJ 08855-1397

Re: K011366
Trade Name: Custom TCI-Combi
Regulation Number: 874.3400
Regulatory Class: II
Product Code: 77 KLW
Dated: May 14, 2001
Received: May 15, 2001

Dear Mr. Slavin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(K) NUMBER (IF KNOWN): **K011366**

DEVICE NAME: **CUSTOM TCI – COMBI**

INDICATIONS FOR USE:

The Custom TCI-Combi is an in-the-ear style electronic, air conduction broad-band noise generator and hearing aid intended to output noise of sufficient intensity and bandwidth to be used for tinnitus habituation therapy and is also suitable for tinnitus masking therapy. Custom TCI-Combi is intended to be used by those individuals who experience tinnitus and desire amplification. This device is fit by a qualified audiologist or other hearing healthcare professional familiar with the diagnosis of tinnitus and subsequent rehabilitation therapy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Karen Baker
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K011366